

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of the claims in the application:

Listing Claims:

- B¹
1. (currently amended): A process for preparing an oral fast-melt pharmaceutical composition, the process comprising
 - (a) a step of wet granulating a drug celecoxib in an amount of about 15% to about 75% by weight of the composition together with a liquid binding agent comprising a saccharide having high moldability, ~~and~~
 - (b) a step of blending with the drug celecoxib a saccharide having low moldability, and
 - (c) a step for inhibiting agglomeration of the drug,wherein steps (a), ~~and (b), and (c)~~ occur in any order or simultaneously to result in formation of granules, wherein the drug has at least one property conferring upon the drug a tendency to agglomerate in the composition and wherein the drug is celecoxib. ~~and wherein the process incorporates means to inhibit agglomeration of the celecoxib.~~
 2. (original): The process of Claim 1 wherein said step (b) occurs prior to or simultaneously with said step (a).
 3. (original): The process of Claim 1 wherein said wet granulating step comprises fluid bed granulation.
- Claims 4-9 (cancelled).
10. (original): The process of Claim 1 wherein said saccharide having low moldability is selected from the group consisting of lactose, mannitol, glucose, sucrose and xylitol.
 11. (original): The process of Claim 1 wherein said saccharide having low moldability is mannitol of powder grade.
 12. (original): The process of Claim 1 wherein said saccharide having high moldability is selected from the group consisting of maltose, maltitol, sorbitol and oligosaccharides having 2 to 6 monosaccharide residues.

13. (original): The process of Claim 1 wherein said saccharide having high moldability is maltose.

Claims 14 – 17 (cancelled)

18. (currently amended): The process of Claim 91 ~~15~~ wherein said wetting agent is added in a total amount of about 0.05% to about 5% by weight of the composition.

19. (currently amended): The process of Claim 91 ~~15~~ wherein said wetting agent is added in a total amount of about 0.075% to about 2.5% by weight of the composition.

20. (currently amended): The process of Claim 91 ~~15~~ wherein said wetting agent is added in a total amount of about 0.25% to about 1% by weight of the composition.

21. (currently amended): The process of Claim 1 wherein the agglomeration inhibiting step further comprising addition of at least one glidant.

22. (currently amended): The process of Claim 21 wherein said at least one glidant is silicon dioxide and/or talc.

23. (currently amended): The process of Claim 21 wherein said at least one glidant is added in a total amount of about 0.05% to about 5% by weight of the composition.

24. (currently amended): The process of Claim 21 wherein said at least one glidant is added in a total amount of about 0.1% to about 2% by weight of the composition.

25. (currently amended): The process of Claim 21 wherein said at least one glidant is added in a total amount of about 0.25% to about 1% by weight of the composition.

26. (cancelled)

27. (cancelled)

28. (currently amended): The process of Claim 1 wherein said drug ~~the celecoxib~~ is present in an amount of about 30% to about 75% by weight of the composition.

29. (currently amended): The process of Claim 1 wherein said drug ~~the celecoxib~~ is present in an amount of about 45% to about 75% by weight of the composition.

30. (original): The process of Claim 1 wherein said saccharide having high moldability is present in a total amount of about 1% to about 10% by weight of the composition.

31. (original): The process of Claim 1 wherein said saccharide having high moldability is present in a total amount of about 1% to about 7.5% by weight of the composition.

32. (original): The process of Claim 1 wherein said saccharide having high moldability is present in a total amount of about 1% to about 5% by weight of the composition.

33. (original): The process of Claim 1 wherein said saccharide having low moldability is present in a total amount of about 10% to about 90% by weight of the composition.

34. (original): The process of Claim 1 wherein said saccharide having low moldability is present in a total amount of about 15% to about 60% by weight of the composition.

35. (original): The process of Claim 1 wherein said saccharide having low moldability is present in a total amount of about 25% to about 50% by weight of the composition.

36. (original): The process of Claim 1 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 2:100 to about 20:100.

37. (original): The process of Claim 1 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 10:100.

38. (original): The process of Claim 1 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 7.5:100.

39. (currently amended): The process of Claim 1, further comprising

(d e) a step of blending said granules with at least one of a lubricant, a sweetening agent and a flavoring agent to form a tableting blend, and

(e d) a step of compressing the tableting blend to form oral fast-melt tablets.

40. (currently amended): The process of Claim 39 wherein parameters are set in said compressing step (e d) to provide tablets having a hardness of about 1 to about 10 kp.

41. (original): An oral fast-melt pharmaceutical composition prepared by the process of any of Claims 1 through 40.

Claims 42- 45. (cancelled)

46. (currently amended) The composition of Claim 101 ~~43~~ wherein said wetting agent is present in an amount of about 0.05% to about 5% by weight of the composition.
47. (currently amended) The composition of Claim 100 ~~43~~ wherein said wetting agent is present in an amount of about 0.075% to about 2.5% by weight of the composition.
48. (currently amended) The composition of Claim 100 ~~43~~ wherein said wetting agent is present in an amount of about 0.25% to about 1% by weight of the composition.
49. (currently amended): The composition of Claim 99 ~~42~~ further comprising a glidant.
50. (currently amended) The composition of Claim 96 ~~49~~ wherein said glidant is silicon dioxide and/or talc.
51. (original) The composition of Claim 49 wherein said glidant is present in an amount of about 0.05% to about 5%.
52. (original) The composition of Claim 49 wherein said glidant is present in an amount of about 0.1% to about 2%.
53. (original) The composition of Claim 49 wherein said glidant is present in an amount of about 0.25% to about 1%.
- Claims 54 – 61 (cancelled).
62. (currently amended): The composition of Claim 42 99 wherein ~~the celecoxib~~ said drug is present in an amount of about 30% to about 75% by weight of the composition.
63. (currently amended): The composition of Claim 42 99 wherein ~~the celecoxib~~ said drug is present in an amount of about 45% to about 75% by weight of the composition.
64. (currently amended): The composition of Claim 42 99 wherein said saccharide having low moldability is selected from lactose, mannitol, glucose, sucrose and xylitol.
65. (currently amended): The composition of Claim 42 99 wherein said saccharide having low moldability is present in an amount of about 10% to about 90% by weight of the composition.
66. (currently amended): The composition of Claim 42 99 wherein said saccharide having low moldability is present in an amount of about 15% to about 60% by weight of the composition.

B1
Cont

67. (currently amended): The composition of Claim 42 99 wherein said saccharide having low moldability is present in an amount of about 25% to about 50% by weight of the composition.
68. (currently amended): The composition of Claim 42 99 wherein said saccharide having low moldability is mannitol of powder grade.
69. (currently amended): The composition of Claim 42 99 wherein said saccharide having high moldability is selected from the group consisting of maltose, maltitol, sorbitol and oligosaccharides having 2 to 6 monosaccharide residues.
70. (currently amended): The composition of Claim 42 99 wherein said saccharide having high moldability is maltose.
71. (currently amended): The composition of Claim 42 99 wherein said saccharide having high moldability is present in an amount of about 1% to about 10% by weight of the composition.
72. (currently amended): The composition of Claim 42 99 wherein said saccharide having high moldability is present in an amount of about 1% to about 7.5% by weight of the composition.
73. (currently amended): The composition of Claim 42 99 wherein said saccharide having high moldability is present in an amount of about 1% to about 5% by weight of the composition.
74. (currently amended): The composition of Claim 42 99 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 2:100 to about 20:100.
75. (currently amended): The composition of Claim 42 99 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 10:100.
76. (currently amended): The composition of Claim 42 99 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 7.5:100.
77. (currently amended): The composition of Claim 99 ~~42~~ that is in the form of a tablet.

B¹
Cont

78. (currently amended): The composition of Claim 77 wherein said tablet ~~that~~ disintegrates within about 30 to about 300 seconds in a standard *in vitro* disintegration assay.

79. (currently amended): The composition of Claim 77 wherein said tablet ~~that~~ disintegrates within about 30 to about 200 seconds in a standard *in vitro* disintegration assay.

80. (currently amended): The composition of Claim 77 wherein said tablet ~~that~~ disintegrates within about 30 to about 150 seconds in a standard *in vitro* disintegration assay.

81. (currently amended): The composition of Claim 77 wherein said tablet ~~that~~ disintegrates within about 5 to about 60 seconds after placement in the oral cavity of a subject.

82. (currently amended): The composition of Claim 77 wherein said tablet ~~that~~ disintegrates within about 5 to about 30 seconds after placement in the oral cavity of a subject.

83. (currently amended): The composition of Claim 77 wherein said tablet ~~that~~ disintegrates within about 5 to about 25 seconds after placement in the oral cavity of a subject.

Claims 84 – 85 (cancelled).

86. (currently amended): A method of treating a medical condition or disorder in a mammalian subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering to the subject a composition of Claim 42 99.

87. (original): The method of Claim 86 wherein said mammalian subject is a human subject.

88. (original): The method of Claim 87 that further comprises combination therapy with one or more drugs selected from the group consisting of opioids and other analgesics.

89. (original): The method of Claim 87 that further comprises combination therapy with an opioid compound selected from the group consisting of codeine, meperidine, morphine and derivatives thereof.

90. (new): The process of Claim 1 wherein said agglomeration inhibiting step comprises (i) adding to the composition at least one inhibitory agent selected from the group consisting of wetting agents and glidants and/or (ii) pre-wetting the drug prior to said step (a).

91. (new): The process of Claim 1 wherein said agglomeration inhibiting step comprises adding to the composition at least one wetting agent.

92. (new): The process of Claim 91 wherein the at least one wetting agent is selected from

1
B
Cont

the group consisting of surfactants, hydrophilic polymers, and clays.

93. (new): The process of Claim 91 wherein the at least one wetting agent comprises at least one surfactant.

94. (new) The process of Claim 93 wherein the at least one surfactant is selected from the group consisting of quaternary ammonium compounds, dioctyl sodium sulfosuccinate, polyoxyethylene alkylphenyl ethers, polyoxyethylene fatty acid glycerides and oils, polyoxyethylene alkyl ethers, polyoxyethylene fatty acid esters, polyoxyethylene sorbitan esters, propylene glycol fatty acid esters, sodium lauryl sulfate, fatty acids and salts thereof, glyceryl fatty acid esters, sorbitan esters, and tyloxapol.

95. (new): The process of Claim 93 wherein the at least one surfactant comprises sodium lauryl sulfate.

96. (new): The composition of Claim 99 wherein said agglomeration inhibiting means comprises at least one wetting agent and/or at least one glidant.

97. (new): The process of Claim 1 wherein the drug is dispersed in the composition.

98. (new): The process of Claim 1 wherein said at least one property is selected from the group consisting of electrostatic, cohesive, low bulk density, low compressibility, and poor flow.

99. (new): An oral fast-melt composition comprising

- (a) a drug in an amount of about 15% to about 75% by weight of the composition;
- (b) a liquid binding agent comprising a saccharide having high moldability, and
- (c) a means for inhibiting agglomeration of the drug,

wherein the drug is uniformly dispersed in the liquid binding agent, wherein the drug has at least one property conferring upon the drug a tendency to agglomerate, and wherein the drug is celecoxib.

100. (new): The composition of Claim 99 wherein said at least one property is selected from the group consisting of electrostatic, cohesive, low bulk density, low compressibility, and poor flow.

101. (new): The composition of Claim 99 wherein the inhibiting means comprises a

C-3320/1/US

Amdt. dated 22 September 2003

Reply to Office Action of 20 May 2003.

wetting agent.

102. (new): The composition of Claim 99 wherein the at least one wetting agent is selected from the group consisting of surfactants, hydrophilic polymers, and clays.

B1
Contd

112